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U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

Telephone: [718] 340-7000 [Ext 5053] Fax: [718]340-7011

July 31, 1997

WARNING LETTER

Certified Mail
Return Receipt Requested

Mr. George Konstandt, President
National Testing Laboratories, Inc.
27-14 39th Avenue
Long Island City, New York 11101

Re: 68-NYK-97

During an inspection of your contract testing laboratory between October 21,1996 and January 23, 1997, our investigators observe serious deviations from the Current Good Manufacturing Practices Part 211), as they relate to your firm's testing of high density polyethylene (HDPE) bottles for conformance with U. S. P. requirements.

The inspection revealed that your firm lacks the basic equipment needed to perform analytical testing pursuant to U. S. P. XXIII Section 661. For example, your firm does not posses an infrared spectrophotometer which is needed to conduct the multiple internal reflectance, colorant extraction, total terephthaloyl moieties, ethylene glycol, and light transmission tests. Your firm also lacked the adequate glassware, reagents and equipment needed to conduct testing on heavy metals, total terephthaloyl moieties, and nonvolatile residues. There was neither laboratory data to support the results of these tests, nor any documentation to demonstrate that such testing was ever performed. Your Chief Chemist was unable to answer questions on how these results were obtained. Our investigators were informed that a contract laboratory was used to perform the Thermal Analysis test. However, they were refused the name of this facility when asked and no documentation was available to support your assertions. Moreover, during the inspection, the investigators encountered several refusals both to allow the inspection of and to provide records as requested.

Based on the our findings during this inspecton, the validity of the HDPE bottle testing conducted by your firm, and any analytical data that your firm generated and supplied to drug manufacturers that indicate testing according to U. S. P. requirements are questionable.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm' s testing procedures. You are responsible for investigating and determining the causes of the violations identified by the FDA. If causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We request that you provide the agency with the names and address of all drug manufacturers for whom you performed bottle testing or supplied any data from 1997 to the present. We further request that a meeting be held between representatives of your firm and the New York District Office to further discuss the specific steps that you have taken or intend to take to correct these violations.

A meeting has been tentatively scheduled for **Friday, August 15, 1997**, at 1:00 P. M. to discuss this matter. Please notify the New York office within five days of receipt of this letter of your availability to attend this meeting. You should be prepared to discuss steps taken to identify and correct any underlying system problems necessary to assure that similar violations will not recur, as well as provide the documentation requested above.

Your reply should be addressed to the U. S. Food and Drug Administration, New York District Office, 850 Third Avenue, Brooklyn, New York 11232, (718)340-7000, X5053, Attention: Anita Fenty, Compliance Officer.

Sincerely,

Brenda Holoman
District Director